PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Peter Buehlmayer *et al*	) Examiner: Brian J. Davis
Serial No.:	10/526,760	) Group Art Unit: 1621
Filed:	March 4, 2005	) Confirmation No.: 6915
Title:	AMINO-PROPANOL DERIVATIVES	) Docket: NOV-10-US

REQUEST FOR REFUND

Mail Stop 16
Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

Applicants respectfully request, on the recommendation of Kendall Jones of USPTO Customer Service, that a refund of $810.00 for a Request for Continued Examination, charged to our Deposit Account 50-4255 on June 10, 2009, be credited to Deposit Account 50-4255.

On June 10, 2009, Applicants filed a Response (copy enclosed) to the Final Office Action mailed March 10, 2009 in the above-identified Application. As part of that Response, in order that their Application would not go abandoned, Applicants included a request for a conditional RCE, clearly specifying that *the Request for Continued Examination would only be effected if*, after the Examiner had reviewed Applicants' Response, *the Application was not allowable or could not be made allowable with minor modifications*. Examiner Davis found the Application to be allowable without further actions, and a Notice of Allowance and Fee(s) Due was mailed on June 23, 2009, thus not requiring such an RCE.

Respectfully submitted,

Dated: July 2, 2009

By Richard A. Elder

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RESPONSE

Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

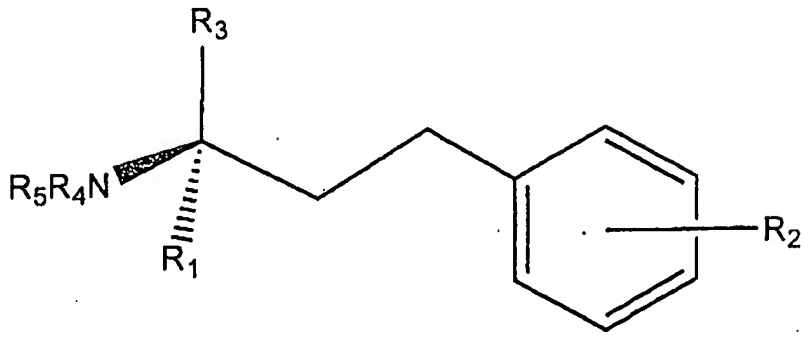
The following is in response to the Final Office Action, mailed March 10, 2009, timely filed within three months of that date, for which no fees are believed due, with a conditional Request for Continued Examination, if the Application is not allowable as a result of this Response or minor changes in a Response to an Advisory Action shortly following this Response and/or as a result of minor amendments that may be timely made between the Examiner and Applicants' Attorney by telephone, as well as with an authorization to charge Deposit Account 50-4255 for any authorized fees related to this filing, including if an RCE is effected, as described above.

Amendments to and Listing of Claims begin on page 2.

Remarks begin on page 5.

AMENDMENTS TO AND LISTING OF CLAIMS

1. (Currently amended) A compound of formula I*:



I*,

wherein

R_1 is methyl;

R_2 is a residue of formula (c): $-Y'-(CH_2)_n-(CF_2)_m-CH_pF_q$ (c),

~~wherein~~ where

Y' is a direct bond, O, CO, CHOH or $C=NOR_6$, wherein R_6 is H, C_{1-4}-alkyl, C_{2-4}-alkenyl, C_{2-4}-alkynyl or benzyl;

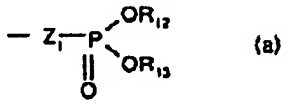
n is 0, 1, 2, 3, 4 or 5;

m is 0, 1, 2, 3, 4, 5 or 6, provided that the sum of n+m is 3-8;

each of p and q, independently, is 0, 1, 2 or 3, with the proviso that p + q =3;

and the chain $(CH_2)_n-(CF_2)_m-CH_pF_q$ contains at least two fluorine atoms and may, optionally, be interrupted by one carbon-carbon double or triple bond, one CO or one-to-three oxygen atoms;

R_3 is $Z-X_2$, ~~wherein~~ where Z is CH_2, CHF, CF_2 or CHMe, and X_2 is OH or a residue of formula (a):



(a)

wherein Z_1 is a direct bond, CH_2, CHF, CF_2 or O, and each of R_{12} and R_{13}, independently, is H or C_{1-4}-alkyl, optionally substituted by 1, 2 or 3 halogen atoms; and

each of R_4 and R_5, independently, is H, C_{1-4}-alkyl optionally substituted by 1, 2 or 3 halogen atoms, or acyl;

in free form or in salt form.

2. (Currently amended) A compound according to Claim 1, ~~wherein~~ where R_2 is selected from the group consisting of

-Y-C_nF_{2n+1}, wherein n=3-8, and Y is CH_2, O or C=O;

-Y-$CH_2C_nF_{2n+1}$, wherein n=1-7, and Y is CH_2, O or C=O;

-Y-$CH_2CH_2C_nF_{2n+1}$, wherein n=1-6, and Y is CH_2, O or C=O;

-Y-$CH_2CH_2CH_2C_nF_{2n+1}$, wherein n=1-5, and Y is CH_2, O or C=O;

~~-Y-$(CH_2)_nF$, wherein n=1-7, and Y is CH_2, O or C=O;~~

-Y-$(CH_2)_nCF_3$, wherein n=1-6, and Y is CH_2, O or C=O;

-Y-$(CH_2)_nCF_2CH_3$, wherein n=1-4, and Y is CH_2, O or C=O;

-Y-$(CH_2)_n(CF_2)_mCHF_2$, wherein n=0-3, m=1-6, n+m = 3-7, and Y is CH_2, O or C=O; and

-Y-$(CH_2)_nC(O)CF_3$, wherein n=1-5, and Y is CH_2, O or C=O.

3-7. (Canceled)

8. (Previously presented) A pharmaceutical composition comprising a compound according to Claim 1, or a pharmaceutically-acceptable salt thereof in association with a pharmaceutically-acceptable diluent or carrier therefor.

9. (Previously presented) A pharmaceutical combination comprising a compound according to Claim 1, in free form or in pharmaceutically-acceptable salt form, and at least one co-agent selected from an immunosuppressant agent, an immunomodulatory agent, an anti-inflammatory agent and a chemotherapeutic drug.

10. (Previously presented) A method for treating disorders or diseases mediated by lymphocytes, and for treating acute or chronic transplant rejection or T-cell-mediated inflammatory or autoimmune diseases in a subject comprising administering to the subject in need thereof an effective amount of a compound

according to Claim 1, or a pharmaceutically-acceptable salt thereof.

11-19. (Canceled)

20. (New) The compound according to Claim 1 selected from the group consisting of:

(R)-2-amino-2-methyl-4-[4-(4,4,5,5,5-pentafluoro-pentyloxy)-phenyl]-butan-1-ol hydrochloride;

(R)-2-amino-2-methyl-4-[4-(6,6,6-trifluoro-hexyloxy)-phenyl]-butan-1-ol hydrochloride;

1-[4-((R)-3-amino-4-hydroxy-3-methyl-butyl)-phenyl]-6,6,6-trifluoro-hexan-1-one; and

(R)-2-amino-2-methyl-4-[4-(7,7,7-trifluoro-heptyl)-phenyl]-butan-1-ol.

REMARKS

Claim 1 has been amended by specifying that R_2 must contain at least two fluorine atoms, as supported in the preferences on page 2, line 27, on page 3, lines 16-19, 21-24 and the structures below line 25, and on page 4, lines 7, 8, 10 and 11, as well as with minor stylistic and/or grammatical changes for clarity.

Claim 2 has been amended by deleting a definition that does not fit the definition of R_2 from amended Claim 1, and with a minor stylistic change for clarity.

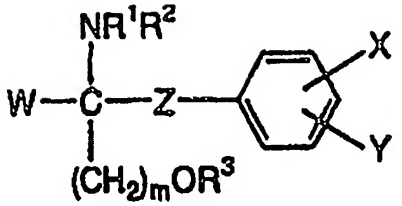
New Claim 20 has been added, claiming the compounds of Example 1, as shown on page 9, lines 15 and 16, Example 6, as shown on page 13, line 8, Example 29, as shown on page 15, lines 30 and 31, and Example 33, as shown on page 17, line 15.

No new matter has been added to the Application as a result of these amendments.

Claims 1, 2, 8-10 and 20 are therefore now currently pending in the instant Application, with a favorable reconsideration of this Application being respectfully requested.

Claims 1, 2 and 8-10 have been rejected under 35USC103(a) as unpatentable insofar as "they read on the species RN=177258-45-6 of WO 9606068".

Published European Patent Application EP0 778 263A1 ('263, believed equivalent to its published International parent, WO 96/06068(A1); Yoshitomi Pharmaceutical Industries, Ltd., with Tetsuro Fujita the first named inventor)

describes benzene compounds of the formula:  and thirty-seven subgeneric compound sets thereof, including seventy-one named such compounds and 747 preferred compounds represented by their chemical components, as well as optically-active isomers thereof, racemates, diastereomers and salts thereof, particularly pharmaceutically-acceptable salts thereof, as well as medicinal compositions, particularly immunosuppressants, containing the same, which compounds are said to be useful as inhibitors/suppressants of organ or bone marrow transplant rejection, as a preventive or remedy for autoimmune diseases and/or inflammatory diseases or disorders, such as articular rheumatism, multiple sclerosis, primary biliary cirrhosis, type I diabetes mellitus, hemolytic anemia, systemic lupus erythematosus, myasthenia gravis, Sjögren's syndrome, uveitis, atopic eczema, Behçet's disease, Crohn's disease, glomerulonephritis, ulcerative colitis, and Evans' syndrome, as well as aplastic anemia, pollinosis, and other conditions, and as an antifungal agent and hair-growth stimulant.

While there are some similarities between some of the '263 compounds and those of the instant invention, the compound RN 177258-45-6 contains an H_3C-$(CH_2)_6$-O group in a position corresponding to the fluorinated moieties of Applicants' R_2. While the Examiner continues to refer to RN 177258-45-6 as "an adjacent homolog of [Applicants'] compound", his unsupported conclusion is neither clear nor scientifically based. The '263 reference does not disclose the specific stereospecificity of the compounds of Applicants formula I* and never even suggests halogens in the R_2 substituent equivalent, much less the two fluorine atoms in Applicants' R_2.

Thus, the '263 reference neither discloses nor at all fairly suggests the novel and unexpected stereospecific, fluorinated compounds of the instant

invention.

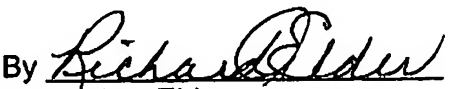
Reconsideration and withdrawal of this rejection is, therefore, respectfully requested.

SUMMARY

In view of Applicants' amendments and arguments, they respectfully believe that all pending Claims, in addition to the recognized allowability of the compound of Example 1, are now in condition for allowance and earnestly solicit such favorable action, with an early Notice of Allowance of the entire Application being issued. If any remaining matters need to be resolved, however, Applicants respectfully request a telephone interview (the undersigned attorney may be contacted at the telephone number set forth below) with the Examiner prior to any adverse action being issued by the Office in response to these arguments, in order to facilitate allowance of the pending Claims.

Respectfully submitted,

Dated: June 10, 2009

By 
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